FEB 1 0 2000

K993190

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Surgical Instrument Services (SIS), Ltd.
P. O. Box
CH-2501 Biel
Switzerland
Phone: 41 (32) 332-91 61
Fax: 41 (32) 332-91 62

b. Contact Person:
Frank Ziemer
Managing Director, New Product Development

c. Date Summary Prepared: January 28, 2000

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Keratome

b. Classification Name: Keratome

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Bausch & Lomb Surgical
Device:	Hansatome Microkeratome
510(k) :	K972808
Date Cleared:	October 24, 1997

Company:	Bausch & Lomb Surgical
Device:	Advance Corneal Shaper - ACS
510(k) :	K913697
Date Cleared:	November 5, 1991

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The SIS, Ltd ACCM Microkeratome is a precision-manufactured instrument designed for cutting a precise corneal disc of preselected thickness and diameter. The design, material and operating principle are very similar to those of the predicate devices.

5. Statement of intended use:

The SIS, Ltd. ACCM Microkeratome is indicated for lamellar resection of the cornea.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Surgical Instrument Systems
Advanced Computer Controlled Microkeratome

TABLE 1
TECHNOLOGICAL COMPARISON

CHARACTERISTICS	SIS-ACCM	Predicate Device Automatic Corneal Shaper	Predicate Device Hansatome Microkeratome
Intended Use	Lamellar Corneal Resections	Lamellar Corneal Resections	Lamellar Corneal Resections
Operating Principle	Electrically driven oscillating blade	Electrically driven oscillating blade	Electrically driven oscillating blade
Suction Ring	Interchangeable heads with fixed thickness plates	One head with interchangeable thickness plates	Interchangeable heads with fixed thickness plates
Blade Drive Source	Electric Motor 6-9V DC (Reusable)	Electric Motor 12V DC (Reusable)	Electric Motor 6-9V DC (Reusable)
Thickness Control	Fixed thickness plate in blade holder; two blade holders available	Thickness Plates	Thickness Plates
Blade Speed	Blade Oscillation 8000 RPM.	Blade Oscillation 7,500 RPM	Blade Oscillation ≥7,500 RPM
Blade Angle	25°	25°	Unknown
Blade Material	Low carbon stainless steel – Disposable, Single-Use	Low carbon stainless steel – Disposable, Single-Use	Low carbon stainless steel – Disposable, Single Use
Blade Sterilization Method	Gamma irradiation	Gamma irradiation	EtO
Flap Diameter	8.5 mm and 9.5 mm	9.0 mm	10 mm
Flap Thickness Options	160μm and 180 um	160μm and 180 μm	160μm and 180 μm
Hinge Location	Nasal or superior	Nasal	Superior
Keratome Mechanism	Dual rectilinear guide rails which are symmetrical.	Dual linear guideways with single linear gear track	Single arcuate gear rack with temporal pivot pin
Console Details			
Electrical	110V or 215V AC	110V or 215V AC	110V or 215V AC
Vacuum Pump	AC Powered	AC Powered	AC Powered
Blade Height Verification	1. Clinically measured with microscope. 2. Quality control check in house concerning mounting	Clinically measured with microscope.	Clinically measured with microscope.
Foot Controls	DC Powered	DC Powered	DC Powered

7. Brief summary of nonclinical tests and results:

The ACCM microkeratome has been designed and tested to applicable safety standards. Parameters related to lamellar resection were validated through extensive preclinical testing. The ACCM microkeratome does not raise any new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2000

Ms. Judy Gordon
Regulatory Consultant to S.I.S.
ClingReg Consulting Services, Inc.
18732 Saginaw
Irvine, CA 92612

Re: K993190
Trade Name: Advanced Computer Controlled Microkeratome (ACCM)
Regulatory Class: I
Product Code: 86 HNO
Regulation: 886.4370 (Keratome)
Dated: January 13, 2000
Received: January 14, 2000

Dear Ms. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K993190

DEVICE NAME: **Advanced Computer Controlled Microkeratome – ACCM**

INDICATIONS FOR USE:

The SIS, Ltd., ACCM microkeratome is a precision-manufactured instrument indicated for lamellar resection of the cornea.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993190

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-9